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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/523,539	03/10/00	GULATI P	VIALO-044650

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EXAMINER	
KIM, Y	
ART UNIT	**PAPER NUMBER**
1631	6

DATE MAILED: 07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/523,539	GULATI ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 3-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 3-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

The specification of the instant application does not comply with the rule and thus is objected to.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite for the recitation of the phrase, "tracking viral load levels from a single source," because it is unclear what the term source refers to. It is unclear whether the term imply a computerized data source, or a patient sample, or etc. For the purpose of prosecution, the source is assumed to be a patient sample.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v.*

Eagle Mfg. Co., 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 3 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 42 of prior U.S. Patent No. 6,245,511. This is a double patenting rejection.

Claim 3 is drawn to an improved method of determining the viral load from a patient, an improvement comprising determining the viral load based upon a microarray output patterns generated from a biological sample taken from the patient.

Claim 42 of the '511 patent is drawn to a method for determining the viral load of a patient, an improvement comprising determining the viral load based upon a biochip output pattern generated from a biological sample taken from the patient.

Although the claim of the '511 patent recite that the load is based upon a biochip output, the term biochip and microarray is well known to be interchangeable in the art.

Therefore, claim 3 is rejected as being coextensive in scope with claim 42 of the '511 patent and double patenting rejection is properly applied.

Claim 4 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 45 of prior U.S. Patent No. 6,245,511. This is a double patenting rejection.

Claim 4 is drawn to an improved method of determining the viral load from a patient, an improvement comprising determining the viral load based upon a microarray output patterns generated from a biological sample taken from the patient, wherein the output pattern of the

microarray is mapped on the viral diffusion curve and the determination of a degree of convergence between the mapped coordinates on the viral diffusion curves is employed.

Claim 45 of the '511 patent is drawn to a method for determining the viral load of a patient, an improvement comprising determining the viral load based upon a biochip output pattern generated from a biological sample taken from the patient, wherein the output pattern of the biochip is mapped on the viral diffusion curve and the determination of a degree of convergence between the mapped coordinates on the viral diffusion curves is employed.

Although the claim of the '511 patent recite that the load is based upon a biochip output, the term biochip and microarray is well known to be interchangeable in the art.

Therefore, claim 4 is rejected as being coextensive in scope with claim 45 of the '511 patent and double patenting rejection is properly applied.

Claim 5 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 45 of prior U.S. Patent No. 6,245,511. This is a double patenting rejection.

Claim 5 is drawn to an improved method of determining the viral load from a patient, an improvement comprising determining the viral load based upon a microarray output patterns generated from a biological sample taken from the patient at different times.

Claim 45 of the '511 patent is drawn to a method for determining the viral load of a patient, an improvement comprising determining the viral load based upon a biochip output pattern generated from a biological sample taken from the patient at different times.

Although the claim of the '511 patent recite that the load is based upon a biochip output, the term biochip and microarray is well known to be interchangeable in the art.

Therefore, claim 5 is rejected as being coextensive in scope with claim 45 of the '511 patent and double patenting rejection is properly applied.

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

06/19/01

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER